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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,006	08/18/2003	Eric G. Lovett	GUID.060PA	2975

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EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
06/15/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/643,006	LOVETT ET AL.	
	Examiner	Art Unit	
	HUONG NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-89,91-93,95-99,101-107,109,112-119 and 121-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-89,91-93,95-99,101-107,109,112-119 and 121-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/2/2011*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the response filed 4/15/2011. The amendment to the specification is acknowledged. Claims 86 and 104 are amended. **Claims 86-89, 91-93, 95-99, 101-107, 109, 112-119, and 121-123** remain pending and under prosecution.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 2/2/2011 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

3. It is noted that the two crossed out NPL references have not been considered because as stated, a copy has not been provided.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 86, 88-89, 91-93, 95-99, 101, 104, 106-107, 109, 112-117, and 121** are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al (US Pat No. 5902250) in view of Cho et al (US Pub No. 20050119711), further in view of Forbes (US Pat No. 5187657).

6. In regard to **Claims 86, 89, 91, and 104**, Verrier et al disclose a method and apparatus for classifying sleep states comprising:

a detector system comprising sensors 12, 14 for detecting conditions related to sleep, the sleep-related conditions comprising a condition associated with a sleep-wake status of a patient such as patient activity or head movement (Col.5: 34-35) and a condition associated with REM sleep such as eyelid movement (Col.11: 29-35);

a classification system 34 for classifying one or more sleep states based on the detected conditions of REM sleep and sleep-wake status (Col.8: 39-41).

7. However, Verrier et al do not disclose classifying the one or more sleep states is performed at least in part implantably and does not disclose providing sleep state informed therapy. Verrier et al also do not disclose the first sensor is disposed on a cardiac rhythm management device which is implanted. It is noted that Verrier et al do disclose the invention also used for monitoring breathing patterns and heart function for the detection of sleep-related conditions (col.12-13). Cho et al disclose an effective implantable cardiac rhythm management device performing the analogous functions of monitoring breathing patterns and heart function for the detection of sleep-related breathing conditions to provide the advantages of constant monitoring without the disadvantages associated with user-related use (¶0010). It is noted that the device of Cho et al must implanted into the chest of the patient, therefore by the pectoral muscles (¶0033). Cho et al also teach that the implantable device for detecting sleep-related conditions provides therapy (¶0016) to effectively treat the patient when certain conditions are detected. Cho et al also disclose a sensor 62 disposed on at least a portion

of the implanted cardiac rhythm management device (¶0043-0044, also see 0016, 0032-0033).

8. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the invention of Verrier et al perform the classifying of one or more sleep states at least in part implantably using a cardiac rhythm management device with a sensor disposed on it as taught by Cho et al to improve the invention by allowing constant monitoring without requiring user involvement for use, wherein when the device is implanted, the sensor would therefore by in communication with the pectoral muscles due to the location of implantation. It would also have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al and Cho et al to provide sleep state informed therapy such as respiratory or cardiac therapy as taught by Cho et al to effectively treat the patient when respiratory or cardiac sleep-related conditions are detected.

9. However, Verrier et al and Cho et al do not disclose the condition associated with REM-sleep comprises sensing a muscle tone in a pectoral region of the patient using the first sensor above. Forbes teaches that it is well known within the art to use a muscle atonia sensor to detect REM sleep (Col.3: 13-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the REM sensed condition of Verrier et al as modified by Cho et al with that of sensing a muscle tone in a pectoral region of the patient as taught by Forbes as an equally as effective means to detect REM sleep in the now implanted device, wherein due to the modification of Verrier et al to be implantable by Cho et al the device with its sensor is

implanted in the chest and therefore by the pectoral muscles allowing sensing of the pectoral muscle tone to effectively determine REM sleep status as taught by Forbes.

10. In regard to **Claims 88, 106-107, and 109**, Verrier et al in combination with Cho et al and Forbes disclose sensing muscle tone using a sensor mechanically coupled to an implantable medical device adapted for implantation in the pectoral region of the patient, wherein the position of the sensor as mounted on the housing is considered a header (see Cho ¶0032 – pacemakers or ICDs).

11. In regard to **Claims 92 and 112**, Verrier et al in combination with Cho et al and Forbes disclose the method and apparatus for detecting the sleep-wake status of the patient by patient activity through sensor 14 but do not specifically disclose detecting the sleep-wake status using an accelerometer. However, Verrier et al do disclose that any suitable sensor for detecting movement can be used in place of sensor 14 (Col.7: 18-20). Because it is widely known that an accelerometer detects movement, it would have been obvious to one of ordinary skill in the art at the time the invention was made to detect the sleep-wake status of the patient of Verrier et al as modified by Cho et al and Forbes above using an accelerometer as an equally as effective sensor for detecting the patient activity and thus sleep-wake status.

12. In regard to **Claims 93 and 113**, Cho et al disclose detecting the conditions related to sleep comprises detecting body posture or torso orientation (¶0045).

13. In regards to **Claims 95-98 and 114-117**, Verrier et al in combination with Cho et al and Forbes disclose the sleep-wake status includes a patient activity signal, and wherein classifying includes determining sleep onset or offset by comparing the patient activity signal to a sleep threshold, as well as determining REM sleep onset or offset by necessarily comparing the pectoral muscle tone or lack thereof – atonia – to an REM sleep threshold (Verrier et al Col.9: 31-Col.11: 35).

14. In regard to **Claims 101 and 121**, Verrier et al in combination with Cho et al and Forbes disclose detecting a cardiac signal and analyzing with an analyzer 34 the cardiac signal on a beat to beat basis (Verrier et al Col.8: 25-Col.10), wherein the therapy system of Cho et al is naturally configured to provide therapy based on both the sleep state classification and the beat to beat cardiac signal analysis for the reasons elaborated above (Verrier et al Col.9: 60-67, Col.12-13).

15. **Claims 87 and 105** are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al in view of Cho et al and Forbes, further in view of Hendricks et al (US Pat No. 6387907).

16. Verrier et al in combination with Cho et al and Young disclose classifying REM sleep but do not disclose doing so by sensing muscle tone using an electromyogram sensor. Hendricks et al teach that REM is characterized by the lack of muscle tone, which can be determined through EMG activity (Col.10: 53-61). Since it is well known in the art that an electromyogram sensor senses EMG activity, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify

the invention of Verrier et al, Cho et al, and Forbes to sense REM sleep through muscle tone using an electromyogram sensor as taught by Hendricks et al as an equally as effective means of classifying REM sleep.

17. **Claims 99 and 118-119** are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al in view of Cho et al and Forbes, further in view of Tchou et al (US Pat No. 6572557).

18. Verrier et al in combination with Cho et al and Forbes disclose the invention above but do not explicitly disclose providing bradycardia pacing therapy. Tchou et al teach effectively providing bradycardia therapy in the presence of the specific arrhythmia (Col.7: 37-54). Since Verrier et al already disclose the detection of heart arrhythmias (Col.12: 2-41) and Cho et al teach the advantages of providing therapy as elaborated above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al as modified by Cho et al and Forbes in the manner above, to advantageously provide bradycardia pacing therapy as taught by Tchou et al in response to a detected cardiac signal indicating the condition, wherein it would have also been obvious to switch to a lower pacing rate based on the sleep state classification because it is known in the art that for example a higher pacing rate may awaken the patient and therefore a lower pacing rater would be desired if the patient is found to be in a sleep condition (Cho et al ¶0008).

19. **Claims 102-103 and 122-123** rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al in view of Cho et al and Forbes, further in view of

Mathews et al (US Pub No. 20030111079), further in view of Cobb (US Pub No. 20040249299).

20. Verrier et al in combination with Cho et al and Forbes disclose the invention above but do not explicitly disclose declaring a hypopnea event if a detected tidal volume falls below a hypopnea threshold. Mathews et al teach that a hypopnea event is determined by comparing tidal volume against a hypopnea threshold, wherein a hypopnea event is determined when the tidal volume falls below, i.e. does not fall on, the threshold (¶0277). Further, Cobb teaches that hypopnea is recognized as falling between normal baseline values and an apneic threshold, i.e. an apnea threshold is lower than a hypopnea threshold (¶0115). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Verrier et al as modified by Cho et al and Forbes in the manner above, to declare a hypopnea event if a detected tidal volume falls below a hypopnea threshold as taught by Mathews et al and to also declare an apnea event if the tidal volume falls below an apnea threshold lower than the hypopnea threshold as taught by Cobb to effectively determine the presence of either hypopnea or apnea and subsequently provide the appropriate therapy.

Response to Arguments

21. Applicant's arguments filed have been fully considered but they are not persuasive. Applicant contends that none of the references teach detecting REM sleep status in a sensor disposed on a cardiac rhythm management device implanted in a pectoral region, particularly that none of the references teach a sensor implanted in a pectoral region of the patient. However, it appears that applicant is taking a piece meal

approach to the references cited. It is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

22. As elaborated above, it is submitted that Verrier et al teach detecting REM sleep status as well as the functions of monitoring breathing patterns and heart function for the detection of sleep-related conditions (col.12-13). Cho et al disclose an effective implantable cardiac rhythm management device performing the analogous functions of monitoring breathing patterns and heart function for the detection of sleep-related breathing conditions to provide the advantages of constant monitoring without the disadvantages associated with user-related use (¶0010). It is noted that the device of Cho et al must implanted into the chest of the patient, therefore by the pectoral muscles (¶0033). Cho et al also disclose a sensor 62 disposed on at least a portion of the implanted cardiac rhythm management device (¶0043-0044, also see 0016, 0032-0033). Due to location of implantation, said sensor would necessarily by placed near said pectoral muscles. Forbes teaches that it is well known within the art to use a muscle atonia sensor to detect REM sleep (Col.3: 13-16). Therefore in combination, when the device of Verrier et al is implanted as taught by Cho et al to improve the invention by allowing constant monitoring without requiring user involvement for use, the sensor disposed on the implanted device would be in communication with the pectoral muscles due to the location of implantation and would thus enable sensing of a muscle tone in a pectoral region of the patient to detect REM sleep as taught by Forbes.

23. It is noted that applicant's specification disclose that "As previously described, the medical device 801 may be implanted into a pectoral region or other suitable location, allowing access to skeletal muscle by the muscle atonia sensor 850" (¶0093). Thus, the rejection above follows the same reasoning in that, a suitable muscle atonia sensor also implanted into a pectoral region will enable determination of REM sleep through sensing of pectoral muscle tone.

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HUONG NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736